AMERICAN
ASSOCIATION
OF BLOOD BANKS

April 27, 1999

Dockets Management Branch (HFA-305)
Food and Drug Administration
5630 Fishers Lane, Room 1061
Rockville, MD 20852

Re: Gamma Irradiation of Blood And Blood Components: A pilot Program for Licensing; Draft Guidance [64 Fed. Reg. November 17, 1999 (Docket No. 980-1218) January 27, 1999]

To Whom It May Concern:

The American Association of Blood Banks (AABB) appreciates the opportunity to submit written comments to the Food and Drug Administration (FDA) on its Draft Guidance concerning the pilot program for licensing of gamma irradiation of blood and blood components intended for transfusion. The AABB appreciates the effort undertaken to prepare and execute the pilot. This is a step forward in the Agency's thinking and planning to streamline the licensure program for both the blood community and for the FDA itself. We expect a commensurate reduction in achieving improvements in the speed of implementing revisions to blood processing.

The AABB is the professional association for approximately 2200 institutions engaged in the collection and transfusion of blood and blood products, including all American Red Cross blood services regions, independent community blood centers, hospital-based blood banks and transfusion services, and more than 8500 individuals engaged in all aspects of blood collection, processing and transfusion. Our members are responsible for virtually all of the blood collected and more than eighty percent of the blood transfused in this country. The AABB's highest priority is to maintain and enhance the safety of the nation's blood supply.

This draft guidance document describes the FDA's current criteria for licensure for manufacturers filing a detailed supplement for gamma irradiated blood components. Concurrently, the document represents criteria for self-certification, under the proposed pilot program, that the blood facility conforms to the Agency's regulatory requirements and thereby qualifies for an exception from filing a detailed supplement. Thus, the AABB assumes that this pilot will be used as the model for future self-certification

8101 Glenbrook Road ♦ Bethesda, MD 20814-2749 ♦ Phone: (301) 907-6977 ♦ Fax: (301) 907-6895
Web site: www.aabb.org ♦ Email: aabb@aabb.org

programs. Any recommendations, changes and/or modifications are appropriately going to be adopted, at least in part, to future self-certification programs.

The AABB wishes to comment on this draft guidance document primarily as it reflects the Agency's current plans for how it "would allow a manufacturer to self-certify conformance to specific criteria as a substitute for the CBER review of information submitted in a BLA supplement."

We believe that the plan as it is described reflects an appropriate guidance as to the content and format of the self-certification. Specifically, we agree that:

- The forms required are appropriate (FDA form 356(h)) and that instructions noted in the guidance document dated July 1998 "Guidance for Industry....." should be followed.
- The Agency's requirement to file a written request pursuant to 21 CFR 640.120 for an exception from the requirement set forth in 21 CFR 601.12(b)(3) to file a detailed supplement that references the applicant's participation in the pilot program is reasonable.
- That the self-certification statement would "indicate that the manufacturer is ready for inspection."

However, while we agree that the manufacturer is ready for inspection, we do not believe that the Agency should feel compelled to "attempt to perform a pre-approval inspection of the manufacturer's manufacturing site(s) within 90 days of receipt of the self-certification statement." While the AABB does not believe that a pre-approval inspection is necessary for the gamma irradiation pilot, we understand the Agency's concern that as a first-time effort, no misunderstanding of the process occur prior to initiating manufacture. An inspection may help avoid potential problems. We also understand that an inspection is routinely required for the current licensure process for gamma irradiation in which the manufacturer has filed a detailed supplement Thus an inspection during the pilot program is consistent with the current process. However, as both the FDA and the blood community become familiar with the self-certification process, the need for a pre-approval inspection should be greatly alleviated and, therefore, not be deemed an automatic step nor should it be incorporated into all such licensure programs.

The FDA has not explicitly defined the contents of the letter to be filed under 21 CFR 640.120. However, the AABB believes that the only information that should be needed is a statement that the facility is requesting the variance based on 21 CFR 640.120 and a statement that the blood facility request meets the requirements for irradiating blood and blood components that are contained in the remainder of the final guidance and the December 1998 Draft Guidance for Industry. The letter should be signed by the individual designated as the senior most official responsible for the blood facility's operations.

The AABB wishes to add a final comment on one of the technical requirements listed under Specific Criteria. Section A.1.b.1, indicates that "the doses of irradiation delivered should be 2500 cGy targeted to the central portion of the container ...." We request changing the requirement as follows:

"The minimum dose of irradiation delivered should be 2500 cGy targeted to the central portion of the container."

This revision would be consistent with practices currently in use by most manufacturers and consistent with the equipment manufacturers' findings as presented to the FDA/CDRH during 510(K) review of the irradiators. This same change should be made to the existing license requirements for the traditional licensing process.

With regard to evaluating the success or failure of the pilot program, the AABB suggests that the evaluation should not be based solely on the number of participants that apply for expedited licensing. Most facilities wishing to obtain licensure for gamma irradiation have already obtained such licensure, so the number of applicants is likely to be small. In addition, the FDA is reminded to consider that applicants are unlikely to represent the same kinds of facilities that would be expected to participate if the pilot involved licensure for a newer technology that is just being widely introduced. Plateletpheresis would be an ideal candidate for self-certification.

The AABB would like to thank you for the opportunity to express our views. We definitely support self certification as a means of licensure. However, as previously discussed, we do not support mandatory prelicense inspections in all cases. The information is available and should be reviewed at the next scheduled CGMP inspection. If you have any questions regarding these comments, please contact, Kay R. Gregory, MS, MT(ASCP)SBB, AABB director of regulatory affairs by phone at (301) 215-6522 or by email at *kayg@aabb.org*.

Sincerely,

Susan L. Wilkinson, EdD, MS, MT(ASCP)SBB
President

AMERICAN
ASSOCIATION
OF BLOOD BANKS

Glenbrook Road • Bethesda, Maryland 20814-2749

Delivered by:

DYNAMEX

Baltimore (410) 281-2103 Maryland (301) 251-8650 Washington D.C. (202) 328-0400 Virginia (703) 914-6700
ADMINISTRATION OFFICES: (202) 328-6419

Dockets Management Branch (HFA-305)
Food and Drug Administration
5630 Fishers Lane, Room 1061
Rockville, MD 20852

301-827-6210